Daniel Duyck email: dduyck@duycklaw.com Duyck & Associates, LLC 111 SW Columbia St., Suite 715 Portland, OR 97201 (503) 764-2030 phone

John Lowther (admitted pro hac vice) email: john@doylelowther.com Doyle Lowther LLP 4400 NE 77th Avenue, Suite 275 Vancouver, WA 98662 (360) 818-9320 phone (360) 450-3116 fax

Attorneys for Plaintiff Barbara Smith

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF OREGON PORTLAND DIVISION

BARBARA SMITH,

Case No.: 3:20-cv-00851-MO

Plaintiff,

v.

PLAINTIFF'S OBJECTIONS TO DEPOSITION TESTIMONY OF SCOTT CLARROCCA

ETHICON, INC., et al.,

Defendants.

General Objection

Mr. Ciarrocca was an Ethicon engineer. Plaintiff generally objects to the majority of Defendants' affirmative designations of this witness. Mr. Ciarrocca is not a retained expert in this case. He was not disclosed as an expert at the time of his depositions, yet the testimony the defense designates is very often expert opinion testimony. Therefore, Plaintiff generally objects to the designated testimony under Federal Rules of Evidence 401-402 and 701-702, as the testimony is impermissible expert opinions, is irrelevant, and is more prejudicial than probative and his testimony will lead to confusion among the jurors.

Defendants' Designations	Plaintiff's Objections
December 3, 2012	
753:11-19	Lines 753:11-19 are duplicative of the testimony in 15:2-15:23 and a waste of time. FRE 403.
754:11-22	Lines 754:11-22 10 are irrelevant as to the witness's length of employment and why he's stayed at Ethicon, and the testimony is an improper opinion for a lay witness as to Ethicon being a well-run company. FRE 401-402, 701-702.
755:1-17	Lines 755:1-17 calls for speculation and hearsay because the witness wasn't personally involved in the Gynemesh selection but testifies to why the mesh was selected and how mesh was best known; the witness is not a testifying expert but renders opinions about mesh characteristics, its track record, and relevant studies. FRE 601-602, 701-703.
756:7-757:20	Lines 756:7-20 is testimony from leading questions. FRE 403, 611. Lines 757:7-14 is duplicative of the testimony in 756:10-757:6 and a waste
	of time. FRE 403. Lines 757:18-20 is speculative and not shown to be made on personal knowledge, but on a "guess." FRE 601-602.
759:11-12	Lines 759:11-12 calls for a response to a leading question, FRE 403, 611.

Defendants' Designations	Plaintiff's Objections
759:15-760:3	Lines 759:15-760:3 are based on speculation and hearsay as to what happened with studies in Europe and the US for which the witness has not shown personal knowledge; the witness is not a testifying expert and opinions about such studies are improper for a law witness. FRE 601-602, 701-702, 801-802.
760:15-761:19	Lines 760:15-761:19 are based on speculation and hearsay as to what happened with labs where physician evaluated Prolift tools, and consultations with physicians, design changes to Prolift tools, the mesh used in studies; the witness is not a testifying expert and opinions about value of data from studies are improper for a lay witness. FRE 601-602, 701-702, 801-802.
761:21-763:20	Lines 761:25-762:11 are based on speculation and hearsay as to the purpose of timelines for projects at Ethicon; this testimony is also irrelevant and a waste of time. FRE 401-403, 601-602, 801-802.
	Lines 762:20-21 are based on speculation and hearsay as to the purpose of timelines for projects at Ethicon; this testimony is also irrelevant and a waste of time. FRE 401-403, 601-602, 801-802
	Lines 763:6-20 are based on speculation and hearsay as to the reasons for urgency for the Prolift product; the testimony concerns opinions on the unmet needs of doctors, the ability of Prolift to meet these needs, and the mesh device's ability to help patients, but the witness is not a testifying expert and has not shown personal knowledge. FRE 601-602, 701-703, 801-802.
764:18-20	Lines 764:18-20 are based on speculation and hearsay as to the steps taken in Prolift product development and testing; the testimony concerns opinions on the necessary steps for product development and testing, but the witness is not a testifying expert and has not shown personal knowledge for all steps and testing. The question is leading and compound. FRE 403, 601-602, 611, 701-703, 801-802.
764:23	Line 764:23 is based on speculation and hearsay as to the steps taken in Prolift product development and testing; the testimony concerns opinions on the necessary steps for product development and testing, but the witness is not a testifying expert and has not shown personal knowledge for all steps and testing. The question is leading and compound. FRE 403, 601-602, 611, 701-703, 801-802.
768:13-769:3	Lines 768:13-769:3 are based on speculation and hearsay as to what the Prolift team believed; the testimony concerns opinions on risk/benefits but the witness is not a testifying expert and has not shown personal knowledge for this topic. The question is leading and would be confusing and misleading to the jury. FRE 403, 601-602, 611, 701-703, 801-802.

Defendants' Designations	Plaintiff's Objections
March 29, 2012	
14:12-16	Lines 14:12-16 are irrelevant and a waste of time as to the witness's resume. FRE 401-403.
15:2-23	Lines 15:17-23 are irrelevant and a waste of time as to the witness's resume. FRE 401-403.
17:15-25	Lines 17:20-24 are based on speculation and hearsay as to what the happened at the exploratory program before the witness joined. FRE 601-602, 801-802.
23:7-19	Lines 23:7-19 are based on speculation and hearsay as to how Ethicon runs its projects and the witness hasn't shown personal knowledge for all Ethicon projects. FRE 601-602, 801-802
45:18-23	Lines 45:18-23 are based on speculation and hearsay as to whether all project members deferred to medical affairs on the question of safety and efficacy. FRE 601-602, 801-802.
45:24-46:16	Lines 46:5-16 are based on speculation and hearsay as to whether all project members deferred to Charlotte Owens on the question of safety and efficacy. FRE 601-602, 801-802.
46:18	Line 46:18 is based on speculation and hearsay as to whether all project members deferred to Charlotte Owens on the question of safety and efficacy. FRE 601-602, 801-802.
60:23-61:13	Lines 61:6-13 are based on speculation and hearsay as to the biocompatibility database and data on Prolene; calls for expert opinion on Gynemesh's biocompatibility but the witness is not a testifying expert and hasn't shown the requisite personal knowledge for a lay opinion. FRE 601-602, 701-702, 801-802.

RECOMMENDATIONS

- 10. The United States and the Defendant recommend as follows:
 - a. The Defendant and the United States have made an AGREEMENT pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), that a specific sentence of probation of at least one year but not more than five years is the appropriate sentence in this case. This agreement takes into account the Defendant's acceptance of responsibility, with no further reduction to occur. The remaining components of the Defendant's sentence, including but not limited to the imposition of a fine, shall be imposed by the Court after the presentation of evidence and/or argument by the parties.
 - b. If the Court accepts the plea agreement, it must inform the Defendant that the agreed upon disposition will be included in the judgment, and the Court is bound by the terms of the plea agreement once the Court accepts the plea agreement.

DEFENDANT'S ADDITIONAL AGREEMENT

- 11. The Defendant recognizes that the United States may demonstrate and argue at sentencing that I made unauthorized purchases and induced the Tribe's payments of approximately \$43,947.99, including \$23,039.23 during the time period from December 15, 2010, to May 19, 2011.
- 12. The Defendant understands the Defendant's obligation to provide the United States

 Pretrial Services and Probation Office with truthful, accurate, and complete information. The

Defendant represents that the Defendant has complied with and will continue to comply with this obligation.

- agreement, the Defendant agrees that, upon the Defendant's signing of this plea agreement, the facts that the Defendant has admitted under this plea agreement as set forth above, as well as any facts to which the Defendant admits in open court at the Defendant's plea hearing, shall be admissible against the Defendant under Federal Rule of Evidence 801(d)(2)(A) in any subsequent proceeding, including a criminal trial, and the Defendant expressly waives the Defendant's rights under Federal Rule of Criminal Procedure 11(f) and Federal Rule of Evidence 410 with regard to the facts the Defendant admits in conjunction with this plea agreement.
- 14. The Defendant recognizes that this plea agreement has already conferred a benefit on the Defendant. Consequently, in return for the benefit conferred on the Defendant by entering into this agreement, the Defendant agrees not to seek a downward departure or variance from the specific sentence of probation of at least one year but not more than five years as agreed to by the parties pursuant to Rule 11(c)(1)(C) of the Federal rules of Criminal Procedure. If the Defendant, in violation of this paragraph, should nevertheless seek a downward departure or variance, including a departure or variance from the guideline Criminal History Category, the United States shall have the right to treat this plea agreement as null and void and to proceed to trial on all charges before the Court.

RESTITUTION

15. The parties agree that, as part of the Defendant's sentence, the Court will enter an order of restitution pursuant to the Mandatory Victim's Restitution Act, 18 U.S.C. § 3663A.

\$5,000, that being the difference between the total unauthorized purchases and the amount that the Jicarilla Apache Nation has already been reimbursed by its insurer, which is immediately payable to the United States District Court Clerk. The Defendant understands that any payment schedule the Court may impose is merely a minimum schedule of payments and not the only method, nor a limitation on the methods, available to the United States to enforce the judgment. The United States Probation Office, or, after the Defendant completes any term of supervised release the Court imposes, the United States Attorney's Office for the District of New Mexico, may revise the monthly payment amount depending on the Defendant's financial circumstances. No later than July 1st of each year after sentencing, until restitution is paid in full, the Defendant shall provide the Asset Recovery Unit, United States Attorney's Office, P.O. Box 607, Albuquerque, NM 87103, (1) a completed and signed financial statement provided to the Defendant by the United States Attorney's Office and/or the United States Probation Office, and (2) a copy of the Defendant's most recent tax returns.

IMMIGRATION REMOVAL AND OTHER IMMIGRATION CONSEQUENCES

17. The Defendant recognizes that pleading guilty may have consequences with respect to the Defendant's immigration status if the Defendant is not a citizen of the United States. Under federal law, a broad range of crimes are removable offenses, including the offense to which the Defendant is pleading guilty. Removal and other immigration consequences are the subject of a separate proceeding, however, and the Defendant understands that no one, including the Defendant's attorney or the district court, can predict to a certainty the effect of the Defendant's conviction on the Defendant's immigration status. The Defendant nevertheless affirms that the Defendant wants to plead guilty regardless of any immigration consequences that the Defendant's

plea may entail, even if the consequence is the Defendant's automatic removal from the United States.

WAIVER OF APPEAL RIGHTS

18. The Defendant is aware that 28 U.S.C. § 1291 and 18 U.S.C. § 3742 afford a defendant the right to appeal a conviction and the sentence imposed. Acknowledging that, the Defendant knowingly waives the right to appeal the Defendant's conviction and any sentence, including any fine, imposed in conformity with this Fed. R. Crim. P. 11(c)(1)(C) plea agreement, as well as any order of restitution entered by the Court. In addition, the Defendant agrees to waive any collateral attack to the Defendant's conviction and any sentence, including any fine, pursuant to 28 U.S.C. §§ 2241 or 2255, or any other extraordinary writ, except on the issue of defense counsel's ineffective assistance.

GOVERNMENT'S ADDITIONAL AGREEMENT

- 19. Provided that the Defendant fulfills the Defendant's obligations as set out above, the United States agrees that:
 - a. Following sentencing, the United States will move to dismiss Counts 2 through 9 of the Indictment.
 - The United States will not bring additional criminal charges against the
 Defendant arising out of the facts forming the basis of the present
 indictment.
- 20. This agreement is limited to the United States Attorney's Office for the District of New Mexico and does not bind any other federal, state, or local agencies or prosecuting authorities.

VOLUNTARY PLEA

21. The Defendant agrees and represents that this plea of guilty is freely and voluntarily made and is not the result of force, threats, or promises (other than the promises set forth in this agreement and any addenda). The Defendant also represents that the Defendant is pleading guilty because the Defendant is in fact guilty.

VIOLATION OF PLEA AGREEMENT

22. The Defendant agrees that if the Defendant violates any provision of this agreement, the United States may declare this agreement null and void, and the Defendant will thereafter be subject to prosecution for any criminal violation, including but not limited to any crime(s) or offense(s) contained in or related to the charges in this case, as well as perjury, false statement, obstruction of justice, and any other crime committed by the Defendant during this prosecution.

SPECIAL ASSESSMENT

23. At the time of sentencing, the Defendant will tender to the United States District Court, District of New Mexico, 333 Lomas Blvd. NW, Suite 270, Albuquerque, New Mexico 87102, a money order or certified check payable to the order of the **United States District Court** in the amount of \$100 in payment of the special penalty assessment described above.

ENTIRETY OF AGREEMENT

24. This document and any addenda are a complete statement of the agreement in this case and may not be altered unless done so in writing and signed by all parties. This agreement is effective upon signature by the Defendant and an Assistant United States Attorney.

AGREED TO AND SIGNED this day of May, 2016.

DAMON P. MARTINEZ United States Attorney

Kristopher N. Hoyghton

Assistant United States Attorney

Post Office Box 607

Albuquerque, New Mexico 87102

(505) 346-7274

(Signatures continue on next page).

I have carefully discussed every part of this agreement with my client. Further, I have fully advised my client of my client's rights, of possible defenses, of the sentencing factors set forth in 18 U.S.C. § 3553(a), of the relevant Sentencing Guidelines provisions, and of the consequences of entering into this agreement. To my knowledge, my client's decision to enter into this agreement is an informed and voluntary one.

Robert Gorence/Christina Cavaler

Attorney for the Defendant

I have carefully discussed every part of this agreement with my attorney. I understand the terms of this agreement, and I voluntarily agree to those terms. My attorney has advised me of my rights, of possible defenses, of the sentencing factors set forth in 18 U.S.C. § 3553(a), of the relevant Sentencing Guidelines provisions, and of the consequences of entering into this agreement.

Vanessa Coñoe aka Vanessa Vicenti

Defendant